

#### **DETAILED ACTION**

1. Claims 1, 3, 5-7, and 18-27 are pending. Applicant's arguments and amendments filed 1/28/08 have been entered. Claims 2, 4, and 8-17 have been canceled.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/28/08 has been entered.

#### **Objections/Rejections Withdrawn**

The following objections/rejections as set forth in the Office action mailed 11/27/07 have been withdrawn:

None.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-7, 20-22, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323).

'578 teaches an aqueous composition for cleaning and wetting a contact lens containing a non-amine polyethyleneoxy-containing material having an HLB value of at least about 18, a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine, a second non-ionic surface active agent, and wetting agent. See Abstract. The cleaning compositions also include buffering agents such as sodium carbonate. Also, the compositions may contain antimicrobial agents in amounts from 0.00001 to about 5% by weight. Suitable antimicrobial agents include polyhexamethylene biguanide, etc. See para. 23-26. The compositions may also contain a sequestering agent such as EDTA. Additionally, supplemental wetting agents may be used such as methyl cellulose, etc. See para. 22. Groemminger does not teach the use of a polyethyleneterephalate container, or an article of manufacture

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comprising a container formed from polyethyleneterephalate and a composition containing surfactants, poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Asgharian et al teach a two-compartment bottle assembly useful in preparing multi-purpose compositions containing an Al-trypsin and disinfectant. These compositions are useful for cleaning and disinfecting contact lenses. See Abstract. The bottle may be made out of materials such as molded polyethylene, polyethyleneterphlate (PET), etc. See column 5, lines 1-5. The disinfecting compositions generally contain one or more antimicrobial agents, a buffer, tonicity agents, a chelating agent, and surfactants (i.e. block copolymers). See column 11, lines 50-69. Specifically, Asgharian et al contain cleaning compositions containing 0.001% Polyquaternium 1, 0.6% boric acid, 0.1% sodium chloride, 0.05% Tetronic 1304, 0.05 disodium edetate, water, etc. See column 14, lines 25-45.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to package the compositions taught by Groemminger in a polyethyleneterephalate container, at the time the invention was made, because Asgharian et al teaches the use of a polyethyleneterephalate container to package similar contact lens cleaning/disinfecting compositions.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, for formulate an article of manufacture comprising a container formed from polyethyleneterephalate and a composition containing surfactants,

poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of Groemminger in combination with Asgharian et al suggest an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition containing surfactants, poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Note that, with respect to the disinfection properties as recited by instant claims 21, 22, and 27, the Examiner asserts that the article of manufacture as suggested by Groemminger in combination with Asgharian et al would have the same disinfection properties as recited by instant claims because Groemminger in combination with Asgharian et al suggest an article of manufacture containing the same container which contains the same components in the same amounts as recited by the instant claims.

Claims 1, 3, 5-7, 19-22, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatia et al (US 6,171,404) in view of Stone et al (US 2002/0039975) and WO99/43363.

Bhatia et al teach contact lens care cleaning compositions comprising carbon dioxide and carbonic acid as a cleansing agent. See Abstract. For example, carbon dioxide could be used as the pressurizing gas in an aerosol can containing purified water, a simple contact lens storage solution, or an aqueous-based multi-purpose contact lens composition, including the commercially available rinsing, disinfecting, and

storage solution known as Opti-free or Opti-One Express. See column 2, lines 45-60.

The contact lens storage solution containing dissolved carbon dioxide may be packaged in a polyethylene terephthalate (PET) bottle under pressure. See column 3, lines 5-25.

As shown in Stone et al, Opti-free express contains 0.001% Polyquaternium-1, 0.45% AMP-95, 0.0005% MAPDA, 0.6% boric acid, 1.2% sorbitol, 0.1% sodium chloride, 0.65% sodium citrate, 0.05% Tetronic 1304, 0.05% disodium edetate, sodium hydroxide, hydrochloric acid, and purified water. See para. 52.

Bhatia et al or Stone et al do not teach the use of PHMB, an amphoteric surfactant or a cellulose derivative such as hydroxyethyl cellulose or an article of manufacture comprising a container made up of polyethylene terephthalate containing a surfactant, PHMB, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

'363 teaches compositions for cleaning and disinfecting contact lenses, wherein the compositions contain a carbonate or bicarbonate salt, a non-carbonate buffer system, an antimicrobial agent, and a nonionic surfactant. Products according to the invention, especially multi-purpose solutions, provide simultaneous disinfection and cleaning of contact lenses including the prevention or removal of protein and lipid deposits and other debris. See Abstract. The compositions may contain an antimicrobial agent such as PHMB, Polyquaternium-1, etc. See page 10, line 5 to page 12, line 15. Additionally, the composition may contain at least one surfactant such as amphoteric, cationic, anionic, or nonionic or combinations thereof. See page 12, lines 20-35. Also, water-soluble viscosity builders may be used which have a tendency to

enhance the lens wearer's comfort by means of a film on the lens surface cushioning impact against the eye. Suitable viscosity builders include hydroxyethyl cellulose, etc.

See page 14, lines 1-15.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use PHMB in the multi-purpose solution disclosed by Stone et al, with a reasonable expectation of success, because '363 teaches the equivalence of PHMB to Polyquaternium-1 as an antimicrobial agent in a similar composition and further, Stone et al teach the use of Polyquaternium-1.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an amphoteric surfactant in the multi-purpose solution disclosed by Stone et al, with a reasonable expectation of success, because '363 teaches the use of amphoteric surfactants alone or in combination with nonionic surfactants in a similar composition and further, Stone et al teach the use of a nonionic surfactant.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use hydroxyethyl cellulose in the composition taught by Stone et al, with a reasonable expectation of success, because '363 teaches that the use of hydroxyethyl cellulose in a similar composition have a tendency to enhance the lens wearer's comfort by means of a film on the lens surface cushioning impact against the eye.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate an article of manufacture comprising a container

made up of polyethylene terephthalate containing a surfactant, PHMB, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success, because the broad teachings of Bhatia et al in combination with Stone et al and '363 suggest an article of manufacture comprising a container made up of polyethylene terephthalate containing a surfactant, PHMB, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Note that, with respect to the disinfection properties as recited by instant claims 21, 22, and 27, the Examiner asserts that the article of manufacture as suggested by Bhatia et al in combination with Stone et al and '363 would have the same disinfection properties as recited by instant claims because Bhatia et al in combination with Stone et al and '363 suggest an article of manufacture containing the same container which contains the same components in the same amounts as recited by the instant claims.

Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323) as applied to claims 1, 3, 5-7, 20-22, 24, 26, and 27 above, and further in view of WO99/43363.

Groemminger and Asgharian et al are relied upon as set forth above. However, neither reference teaches the use of an amphoteric surfactant in addition to the other requisite components of the composition as recited by the instant claims.

'363 is relied upon as set forth above.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an amphoteric surfactant in the multi-purpose solution disclosed by Groemminger, with a reasonable expectation of success, because '363 teaches the use of amphoteric surfactants alone or in combination with nonionic surfactants in a similar composition and further, Groemminger et al teach the use of a nonionic surfactants.

Claims 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323) or Bhatia et al (US 6,171,404) in view of Stone et al (US 2002/0039975) and WO99/43363 as applied to the rejected claims above, and further in view of Brincat (US 2002/0162863).

Groemminger, Asgharian et al, Bhatia et al, Stone et al, and '363 are relied upon as set forth above. However, none of these references teach that the polyethylene terephthalate container is clear as recited by the instant claims.

Brincat teaches a refillable container adapted to facilitate the purchase of consumer products and the selective discharge thereof. See Abstract. The containers may be made of polyethylene terephthalate and may contain substances such as contact lens solutions, etc. See para. 85 to para. 130. The containers may be clear allowing for the visual identification of the contents thereof. See claim 11.

It would have been obvious to formulate the PET containers taught by Asgharian et al or Bhatia et al as clear, with a reasonable expectation of success, because Brincat

teaches the use of a clear (i.e., transparent) PET container for contact lens solutions and Asgharian et al or Bhatia et al teach the use of PET containers in general.

***Response to Arguments***

With respect to the rejection of the instant claims under 35 USC 103(a) using Groemminger in combination with Asgharian et al, Applicant states that experimental data has been presented in a new Declaration filed under 37 CFR 1.132 that demonstrates the advantages of packaging a contact lens disinfecting solution that comprises the recited range of PHMB and one or more of the recited surfactants in a PET bottle compared to packaging the same solution in a HDPE bottle. In response, note that, the Examiner asserts that Applicant has once again provided the data as part of the attorney's arguments, which is not an appropriate means for submission of data attempting to show the unexpected and superior properties of the claimed invention. Specifically, Tables 1-11, which contain all the data that attempt to show the unexpected and superior properties of the claimed invention in comparison to articles of manufacture falling outside the scope of the instant claims, have been provided as part of the attorney's arguments and not as part of the 132 Declaration. The actual Declaration filed under 37 CFR 1.132 provides only a short and inaccurate description of the data and no numeric evidence.

Note that, objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of

the prior art derived the disclosed subject matter from the applicant. See, for example, In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). Additionally, the arguments of counsel cannot take the place of evidence in the record. In re Schultze, 346, F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01(c). The Examiner asserts that in order to be persuasive, any data presented attempting to show evidence of unexpected results must be in the form of an appropriate affidavit or declaration. Thus, as stated previously, the data presented as part of the attorney's arguments in the instant case is moot and has not been considered, and the rejection of the instant claims under 35 USC 103(a) using Groemminger in combination with Asgharian et al has been maintained.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above.

Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory R. Del Cotto/  
Primary Examiner, Art Unit 1796

/G. R. D./  
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